REMARKS

Claims 1-10, 12, 13 and 16-25 are pending in this application. Claims 2, 4-7, 9-11, 14-22, and 24 are canceled herein without prejudice or disclaimer. Claims 1 and 23 are amended herein and new claim 26 is added. Support for these amendments can be found in the language of the original claims and throughout the specification, at least, for example, original claims 1, 2 and 10; on page 2, lines 9-12 and lines 21-23; on page 3, lines 4-5; on page 6, lines 4-5; on page 30, lines 11-12; and in Table 1. Thus, no new matter is added by these amendments and new claim and applicants respectfully request their entry and consideration.

I. Rejection under 35 U.S.C. § 112, first paragraph.

The Action states that claims 1-3, 8, 10, 12, 13 and 23-25 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description in the specification. Specifically, the Action states that applicants' argument that the term "deleted" can include an ACCase containing more of the sequence than the BC domain, but the other domains are rendered non-functional using common molecular biology techniques is unpersuasive because "the specification on page 6 recites that the terms 'deleted' or 'deletion' means total deletion of the specified segment." Action, page 4. Applicants respectfully traverse this rejection and specifically disagree with this interpretation of the specification.

Claim 1 is amended herein to recite an isolated peptide comprising an Acetyl CoA carboxylase (ACCase) having a nonfunctional biotin binding domain, having a nonfunctional carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide is a monomer and binds to soraphen, and wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase.

Claim 23 is amended herein to recite an isolated peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, wherein said functional biotin carboxylase domain is a monomer and binds to soraphen and wherein said functional ACCase biotin carboxylase domain is selected from the group consisting of: mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase.

Page 6 of the specification wherein the "deleted" or "deletion" are defined states "[a]s used herein, the terms 'deleted' or 'deletion' mean either total deletion of the specified segment **or the deletion of a sufficient portion of the specified segment to render the segment inoperative or**

nonfunctional (*e.g.*, does not encode a functional peptide, wherein functional is defined as the ability to bind soraphen), in accordance with common usage." (Specification, paragraph bridging pages 6-7; emphasis added). Clearly, such a definition would include an ACCase with more than the sequence of the BC domain; it could include a nonfunctional biotin binding domain and a nonfunctional carboxy transferase. While applicants assert that the terms deletion and deleted as defined in the specification would include nonfunctional in addition to a total deletion, in order to expedite prosecution of the application, claim 1 and claim 23 are amended herein to recite a nonfunctional biotin binding domain and a nonfunctional carboxy transferase.

In addition, the Action states that the specification teaches only a single peptide consisting of ACCase biotin carboxylase domain (SEQ ID NO:2) and does not teach other species comprising a peptide comprising an ACCase having a deleted biotin binding domain, having a deleted carboxy transferase domain and having a functional biotin carboxylase that binds to soraphen. Action page 5.

Applicants respectfully submit that the specification provides at least 63 peptides (SEQ ID NOS:2, 4, 6, 8, 10, 12, 14, 16 and 17-71) that are exemplary of the ACCase peptides of the invention having a nonfunctional biotin binding domain, having a nonfunctional carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide is a monomer and binds to soraphen, and wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase. Applicants respectfully submit that these examples are a sufficient representation of the genus of peptides as claimed herein in order to meet the written description requirement as set out in both *Enzo* (*Enzo Biochem, Inc. v. Gen-Probe Inc.* 296 F.3d 1316 (Fed. Cir. 2002)) and *Eli Lilly* (*University of California v. Eli Lilly & Co.* 119 F.3d 1559 (Fed. Cir. 1997)).

Additionally, applicants submit that a description in a claim of a lack of function or a deletion of a domain or portion of a domain such that it lacks function provides sufficient description such that one of skill in the art would understand the scope of what is claimed. As discussed in applicants previous response of August 13, 2007, the U.S. Court of Appeals for the Federal Circuit (CAFC) in *Invitrogen Corp. v. Clontech Laboratories, Inc.,* (429 F.3d 1052, 77 U.S.P.Q.2d 1161 (Fed. Cir. 2005)) confirmed that such a claim can satisfy the written description requirement. The representative claim considered for the issue of written description by the *Invitrogen* court was claim 1 of U.S. Patent No. 6,063,608, which recites

> [a]n isolated polypeptide *having DNA polymerase activity* and substantially reduced RNase H activity, wherein said polypeptide is encoded by a modified reverse transcriptase nucleotide sequence that encodes a modified amino acid sequence resulting in said polypeptide *having substantially reduced RNase H activity,* and wherein said nucleotide sequence is derived from an organism selected from the group consisting of a retrovirus, yeast, Neurospora, Drosophila, primates and rodents.

Id. at 1072.

Furthermore, dependent claims 3 and 4 of the Invitrogen patent recite "[t]he polypeptide of claim 1, wherein said polypeptide has no detectable RNase H activity" and "[t]he polypeptide of claim 1, wherein said polypeptide lacks RNase H activity," respectively.

Id. at 1074.

The court stated that "with these patents Invitrogen thereby claims a compound (the polypeptide or genetically engineered RT) in terms of biologic functions (DNA polymerase and Rnase H activity)." *Id.* at 1072 (emphasis added).

The defendant, Clontech, argued that the decisions in *University of California v. Eli Lilly & Co.* (119 F.3d 1559 (Fed. Cir. 1997)) and *Fiers v. Revel* (984 F.2d 1164 (Fed. Cir. 1993)) required that the claims recite the sequence disclosed in the specification. The court disagreed with this interpretation and stated that in addition to the sequence recited in the specification, at the time of the invention, sequences of RT genes were known and members of the RT gene family shared significant homologies from one species to another. Further, the court found that in both *Eli Lilly* and *Fiers* that the patent specifications at issue did not identify the sequence (structure) of any embodiment of DNA claimed therein. In contrast, the description for the Invitrogen patent recites both DNA and amino acid sequences of a representative embodiment of the claimed RT enzyme.

Similar to the Invitrogen patent, the present application discloses representative embodiments of the claimed enzyme (ACCase). In fact, the present specification discloses many more representative amino acid and nucleic acid sequences than were provided in the Invitrogen patent specification. Further, as presented in applicants' previous response dated August 13, 2007, sequences of ACCases were known in the art at the time the present application was filed and significant homology was shown to exist between ACCases from different species.

Moreover, as discussed in Applicants' August 13, 2007 response, the District Court and the CAFC in the *Invitrogen* case found that such a recitation of "no detectable" or "lacks" satisfied the written description requirement of § 112. *Id.* at 1074, 1079. Similar to the *Invitrogen* case, based on the representative structures and the description provided in the specification of the present invention, as well as the information about ACCases generally known in the art, one of skill in the art would know what was encompassed by the presently claimed invention of an isolated peptide comprising an AcetylCoA carboxylase having a nonfunctional biotin binding domain, having a nonfunctional carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide is a monomer and binds to soraphen, and wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase. Accordingly, applicants respectfully submit that the specification of presently claimed invention satisfies the written description requirement.

For the forgoing reasons, it is respectfully submitted that the rejection of claims 1-3, 8, 10, 12, 13 and 23-25 under 35 USC § 112, first paragraph, is overcome and therefore should be withdrawn.

II. Rejections under 35 U.S.C. § 102.

A. Bailey et al.

The Action states that claims 1-3, 10, 12 and 23-25 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Bailey et al. (*Mol. Gen. Genet.* 249: 191-201 (1995)). Action, page 5. The Action states that applicants' previous arguments were non-persuasive because the claims do not set forth any structural details of a peptide that binds to soraphen, SEQ ID NO:2. Action, page 6. The Action further states that Bailey teaches ACCase from *Ustilago maydis,* which contains BC domain that binds to soraphen. *Id.* Applicants respectfully disagree.

Under Section 102, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" M.P.E.P. § 2112 (citations omitted). Therefore, in relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Id.*

As pointed out in applicants previous responses dated January 11, 2007 and August 13, 2007, Bailey et al. does not disclose each and every element of the present invention, expressly or inherently. Bailey et al. describes a fragment of the coding region of *Ustilago maydis* ACCase, which includes a small portion of the BC domain (Bailey et al., Figure 2). The Action alleges that the fragment of Bailey et al. inherently discloses a BC domain that binds to soraphen with a dissociation constant from 10^{-7} to 10^{-14} M. The Examiner provides no basis in fact or technical reasoning for why one of ordinary skill in the art would consider a fragment such as that disclosed in Bailey et al. to inherently disclose a BC domain that binds to soraphen with a dissociation constant from 10^{-7} to 10^{-14} M. Furthermore, applicants have repeatedly presented a published research paper by Shen et al. that contradicts such a theory of inherency. The Shen et al. reference determined experimentally which amino acid residues are involved in soraphen binding. A comparison of the data presented in Shen et al. with the amino acid sequence of the fragment presented in the Bailey et al reference clearly shows that the residues involved in soraphen are not present in Bailey et al. fragment (see, in particular, the response dated January 11, 2007).

Moreover, in addition to failing to teach or suggest a BC domain that binds to soraphen, Bailey et al. fails to teach or suggest an isolated peptide comprising an acetyl CoA carboxylase (ACCase) having a nonfunctional biotin binding domain and having a nonfunctional carboxy transferase domain, wherein said peptide is a monomer. On the contrary, if anything, Bailey et al. only discusses functional domains of ACCase. Further, those of ordinary skill in the art would know that typically ACCases and their subunits exist as dimers or tetramers not monomers as claimed by the present invention (see for example, Specification, page 1; Nikolau et al., *Arch. Biochem. Biophys*. 414: 211-222 (2003); Schulte et al., *Proc. Natl. Acad. Sci*. 94: 3465-3470, 3465 (1997); Tong et al., *Cell. Mol. Life Sci.* 62: 1784-1803, 1786 and Fig. 6).

Accordingly, applicants respectfully submit that Bailey et al. fails to disclose each and every element of the presently claimed invention. Therefore, applicants submit that claims 1-3, 10, 12 and 23-25 are novel over Bailey et al. and thus, respectfully request that the rejection be withdrawn.

B. Schulte et al.

The Action states that claims 1-2, 10, 12 and 23-24 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Schulte et al. (*Proc. Natl. Acad. Sci.* 94: 3465-3470 (1997)). Action, page 6. Specifically, the Action states that applicants' arguments that Schulte et al. does not teach a peptide that binds to soraphen are not persuasive because the claims as set forth do not recite the BC domain structure. *Id.* The Action further states that in the absence of such structural details the art reads on the claimed invention and inherently comprises the claimed dissociation constant. *Id.* Applicants respectfully traverse this rejection.

As discussed previously, a description in a claim of a lack of function or a deletion of a domain or portion of a domain such that it lacks function provides sufficient description such that one of skill in the art would understand the scope of what is claimed (see above discussion of *Invitrogen v. Clonetech*). Thus, applicants submit that the claimed invention is distinguished over the cited art without inclusion of further structural recitations.

Furthermore, Schulte et al. is cited solely for its discussion of a deduced amino acid sequence of the BC domain of yeast ACCase as presented in a dendrogram (Schulte et al., Figure 5). The Schulte et al. reference provides no sequence or other information about the BC domains discussed therein. The only information about these BC domains must be obtained from the original sources. In the case of the yeast BC domain, the original source is Al-Feel et al. (*Proc. Natl. Acad. Sci.* 89: 4534-4538 (1992)). In the Al-Feel et al. reference, a yeast FAS3 gene was cloned and the nucleotide sequence of the entire gene was reported. In Al-Feel et al. a putative BC domain was determined based on a deduced amino acid sequence comparison with ACCase from rat and chicken. Since Schulte et al. does not present any amino acid or nucleic acid sequence of any of the BC domains that are used to prepare the dendrogram, one of ordinary skill in the art could not determine from this reference what portion of the yeast BC domainis presented in Schulte et al. Accordingly, since it is clear from Shen et al. (discussed in detail above) that in order to bind soraphen particular amino acid residues must be present, one of ordinary skill in the art could not determine from Schulte et al. whether the BC domain presented therein was capable of binding to soraphen and if so, whether it has a soraphen dissociation constant of 10^{-7} to 10^{-14} M.

As discussed previously, to establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that

it would be so recognized by persons of ordinary skill. Nothing in Schulte et al. (or in Al-Feel et al.) indicates that the putative BC domain discussed in Schulte et al. binds soraphen or has a soraphen dissociation constant of from 10^{-7} to 10^{-14} M such that one of ordinary skill in the art would recognize such an alleged inherent property. Further Schulte et al. does not disclose an isolated peptide comprising an ACCase having a nonfunctional biotin binding domain and a nonfunctional carboxytransferase domain, wherein said peptide is a monomer, as claimed in the present invention.

Accordingly, Schulte et al. fails to disclose or suggest each and every element of the presently claimed invention. Thus, applicants respectfully submit that this rejection is overcome and respectfully request that it be withdrawn.

III. Rejection under 35 U.S.C. § 103.

The Action states that claims 1-3, 10, 12, 13 and stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bailey et al. or Schulte et al. in view of Trubetskoy et al., U.S. Pat. 7,098,032.

As discussed above, neither Bailey et al. nor Schulte et al., alone or in any combination, teach or suggest each of the recitations of the claimed invention. In the previous Office Action, dated October 13, 2006, it was stated that the teachings of Bailey et al. and Schulte et al. are those as described in the section 102 rejections (page 6). These rejections each include a discussion of the BC domains of Bailey et al. and Schulte et al. that are alleged to inherently bind soraphen with a dissociation constant of from 10^{-7} to 10^{-14} M. As discussed above, such inherency cannot be shown. Further, applicants respectfully submit that, as stated in the M.P.E.P., a reference cannot be relied upon for allegedly inherent teachings to support a rejection under 35 U.S.C. § 103. Specifically, it is stated in § 2141.02 of the M.P.E.P., with a citation to *In re Rijckaert*, that "[o]bviousness cannot be predicated on what is not known at the time an invention was made, even if the inherency of a certain feature is later established." 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). Thus, the use of Bailey et al. or Schulte et al. for their allegedly inherent teachings as a necessary basis for this obviousness rejection renders the rejection improper and applicants request that it be withdrawn for at least this reason.

Further, Trubetskoy et al. fails to remedy the deficiencies of Bailey et al. or Schulte et al. Trubetskoy et al. was cited by the Examiner solely for allegedly teaching the pH range found in

claim 13 of the present invention. Therefore, Bailey et al. and/or Schulte et al., alone or in combination with Trubetskoy et al., cannot support a rejection under § 103(a). Accordingly, Applicants respectfully request that this rejection be withdrawn.

IV. New Claim 26.

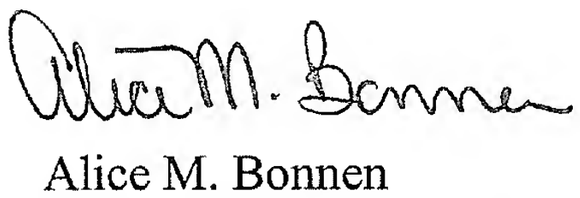
New claim 26 is added herein. Support for this claim can be found in the language of the original claims and throughout the specification, as set forth above. This claim is believed to be free of the pending rejections for the same reasons set forth above explaining why claims 1-10, 12, 13 and 16-25 are free of the pending rejections and its entry and allowance is respectfully requested.

Conclusion

In view of the amendments and remarks presented herein, Applicants respectfully submit that this application is in condition for allowance, which action is respectfully requested.

The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of $810.00 as fee for a Request for Continued Examination. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



Alice M. Bonnen
Registration No.: 57,154

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

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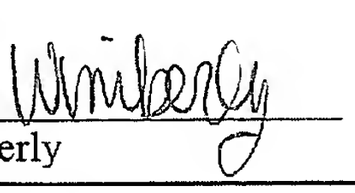

Claire Wimberly